UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, DC

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OFFICE OF
POLLUTION PREVENTION & TOXICS

MEMORANDUM

SUBJECT: Discontinuation of Exposure Modeling Thresholds in New Chemical Reviews

DENISE KEEHNER Digitally signed by DENISE KEEHNER
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FROM: Denise M. Keehner, Director
Office of Pollution Prevention and Toxics (OPPT)
Office of Chemical Safety and Pollution Prevention (OCSPP)

TO: Office of Pollution Prevention and Toxics
New Chemicals Division (NCD) Management Team

Madison Le, Director, New Chemicals Division
Shari Barash, Acting Deputy Director
Loraine Passe, Senior Advisor
Louis Scarano, Senior Advisor
Keith Salazar, Immediate Office
Tracy Williamson, Chief, Industrial Chemistry Branch
Jeffrey Gallagher, Acting Chief Risk Assessment Branch 1
Ariel Hou, Chief, Risk Assessment Branch 2
James Alwood, Acting Chief, Risk Management Branch 1
Rebecca Edelstein, Chief, Risk Management Branch 2

This memo implements and explains my reasons for discontinuing the use of the exposure modeling thresholds that are currently used in new chemical reviews. My decision is based on reasons explained in the remainder of this memo.

I was recently briefed on an issue initially raised by staff of whether the New Chemicals Program (NCP) should continue to utilize exposure modeling thresholds in the review of new chemicals. In short, the NCP explained the thresholds and how they are currently used, the background and history (as is currently understood) associated with their initial development and staff work evaluating whether the use of these thresholds is appropriate in all cases. Based on this briefing as well as input from senior science advisors Dr. Anna Lowit and Dr. Stan Barone, I have made the decision to discontinue the use of the exposure modeling thresholds that are currently used in new chemical reviews (see Appendix for background on existing policy). To effectuate this policy change, NCP will need to make some minimal changes to the coding of our modeling systems to remove the thresholds and will need to update standard operating procedures and

training materials for exposure and human health risk assessors. NCP will work with staff and contractors to implement this policy change as soon as feasible and communicate out to all managers and staff as to the effective date for implementation.

The policy to use exposure modeling thresholds was put in place around 1995 and was informed by science and the experience of the NCP between its creation in the 1970's and 1995. That is, through the experience of reviewing over a thousand PMNs each year, the Program observed that when a chemical is released in relatively small amounts to air or from landfills, that the risks posed by such releases were small and were typically not considered to be unreasonable. Program management decided not to expend constrained programmatic resources quantifying exposures and risks associated with these releases. In the 1990's the NCP received over a thousand PMNs each year and routinely quantifying potential risks associated with these small releases (using the methods available at that time) was not considered to be a good use of already constrained program resources.

Since then, due in part to the automation of modelling, it has become less burdensome to complete these calculations. In addition, the number of PMNs declined significantly after the 2016 Lautenberg amendments to TSCA, reducing the total volume of this work. Moreover, understanding the potential risk to overburdened and underserved communities is a priority and removing the modeling thresholds in the review of new chemicals will help us and overburdened and underserved communities better understand the potential risks posed by releases of chemicals to these communities. President Biden's Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, calls on Federal agencies to advance equity, including by reviewing and revising as needed government policies and programs impacting underserved communities. Completing the modeling for general population exposure from fugitive air and stack releases and landfill releases will allow for a more fulsome understanding of the potential risks to fenceline communities. In light of these considerations, it is reasonable for the Program to discontinue the use of these modeling thresholds.

As indicated above, to implement these changes, NCP will need to make some changes to the coding of our modeling systems to remove the thresholds and will need to update standard operating procedures and training materials for exposure and human health risk assessors to calculate risks where risks were not calculated in the past due to threshold cutoffs. NCP will work with staff and contractors to implement this policy change as soon as feasible.

cc: Michal Freedhoff, Assistant Administrator, OCSPP
Rick Keigwin, Deputy Assistant Administrator, OCSPP
Tala Henry, Deputy Office Director, OPPT
Anna Lowit, Acting Senior Science Advisor, OPPT
Iris Camacho, Immediate Office, OPPT
Stan Barone, Senior Science Policy Advisor for Chemical Safety, OCSPP

Enclosure: Appendix: Background on Exposure Modeling Threshold Policy

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Since approximately 1995, OPPT has applied exposure modeling thresholds (see conditions below) when estimating exposures for the general population as part of the risk assessment for all Section 5 submissions [e.g., low volume exemptions (LVEs), premanufacture notices (PMNs), significant new use notices (SNUNs)].

The acute and chronic release thresholds were as follows:

- Acute release threshold (used for all non-cancer endpoint evaluations):
    - 0.54 kg/site-day for fugitive air releases, and
    - 28 kg/site-day for stack incineration releases.
- Chronic release threshold (used for all cancer endpoint evaluations):
    - 86 kg/site-year for fugitive air releases,
    - 698 kg/site-year for stack incineration releases, and
    - 26 kg/site-year for landfill releases.

NCD previously did not quantify exposure to the general population when environmental releases in the Initial Review Engineering Report (IRER) were below these thresholds. In this situation, the human health risk assessment and risk determination document characterized the unquantified exposures as "negligible (below modeling thresholds)."

The application of exposure modeling thresholds is documented in the exposure team's Standard Operating Procedure (SOP) titled "New Chemical Workflow Summary" and in the exposure contractor's Quality Assurance Project Plan (QAPP). Additionally, these thresholds were programmed into the New Chemicals Exposure Model (NCEM) and the New Chemical Review (NCR) application such that when fugitive air, incineration and landfill releases were below the threshold values, no exposure modeling would be run for the general population assessment.

To implement these changes, NCP will need to make some changes to the coding of our modeling systems to remove the thresholds and will need to update standard operating procedures and training materials for exposure and human health risk assessors to calculate risks where risks were not calculated in the past due to threshold cutoffs.